Fax

To: MITAL B. PATEL From: SUNIL DHUPER, MD

Fax: 703 306 4520 Pages: 73 (including cover sheet)

Phone: 703 306 5444 Date: 5/20/03

Re: Application # 10/072,282 CC:

☐ Urgent ☑ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

FAX RECEIVED
MAY 20 2003
GROUP 3700

• Comments: Dear Examiner Patel,

As per our conversation, I am faxing 73 pages (including the cover sheet) regarding application 10/072,282. The inclusions are as follows:

1 Page - Express Mail Receipt

1 Page - US Postal Office Transaction Receipt ($17.85 charged)

1 Page - Confirmation from US Postal Service regarding delivery

7 Pages - Response from USPTO (2/4/03)

6 Pages - Response from USPTO (3/6/03)

24 Pages - My response to the two letters from USPTO

17 Pages - Revised Application

15 Pages - Marked up old Application.

If there are any questions, please do not hesitate to call me. Thanks.

3761

#5 OL 5-28

UNITED STATES POSTAL SERVICE.

Date: 04/30/2003

Fax Transmission To: Postal Customer
Fax Number: 718-519-3734

Dear Postal Customer:

The following is in response to your 04/30/2003 request for delivery information on your Express Mail item number ET073990941US. The delivery record shows that this item was delivered on 03/12/2003 at 11:07 AM in WASHINGTON, DC 20231 to V REISTER. There is no delivery signature on file for this item.

Thank you for selecting the Postal Service for your mailing needs. If you require additional assistance, please take this receipt to your local Post Office or postal representative.

Sincerely,

United States Postal Service

To:

Patel, Mital B.

Examiner

United States Patent and Trademark Office

Washington, D.C. 20231

From:

Sunil Dhuper, MD

47 Red Ground Road

Old Westbury, New York 11568

Dear Examiner Patel:

First of all, I would like to thank you for taking time out of your busy schedule to answer some of my questions in relation to the application No. 10/072,282. In your communication dated 2/4/03 (copy enclosed) you have raised 12 very pertinent issues that need further clarification. I had the opportunity to address the majority of those issues in our oral discussion on 2/13/03 .The same has been indicated in your follow-up correspondence as well (copy enclosed). However, there are some issues that could not be discussed in depth. This response addresses all the issues that we discussed orally as well as offers a written clarification on some of the issues that we did not have a chance to address. Also enclosed is a copy each of the revised application with amendments

(clean version) and the original application with amended sections underlined (marked up version). I hope you will find this response satisfactory.

In your correspondence dated 2/4/03, you have requested a clarification on altogether 12 questions. The first three questions (1-3) are related to the 'DRAWING SECTION'. Please note that there are no amendments in this section of my revised application and all the drawings and characters remain unchanged. I have, however, made necessary revisions in the text with a fuller description (please refer to the section 'amendments to the detailed description of the invention' in the clean version of my revised application) in order to match the text characters with the corresponding characters described in the drawings.

Questions 4,5,6 and 7 are related to the 'CLAIMS REJCTION SECTION'. As per our discussion and your invaluable suggestions, I have re-written the claims(please refer to the section 'amendments to the claim(s)' in the clean version of the revised application). I hope that the revisions will now satisfy the requirement.

Questions 8,9,10 and 11 are also related to the 'CLAIMS REJECTION SECTION' of the correspondence. In our oral discussion, I pointed out the pertinent features of Matson's invention and how the invention is fraught with numerous problems. I also discussed the significant differences between Matson's invention and ours and how our invention is a major improvement over Matson el al's invention and overcomes all the problems associated with this device as well as with all the pre-existing inventions in aerosol delivery. A detailed discussion on this subject matter is outlined in the pages to follow.

Last of all, question 12 is related to the 'CONCLUSION SECTION' of the correspondence. In this section, you have cited several related reference articles. Even though we a had a chance to talk about some of the reference articles, the discussion was brief. In the pages to follow, I have discussed each and every one of those reference articles in depth. The discussion will point out the objective and pertinent features of those inventions, the differences between those inventions and our invention, the problems associated with other inventions and how our invention is a major improvement over all the pre-existing devices.

Discussion

1. Catheter Device for Aerosol Delivery-Pitfalls and Problems

The 'catheter device for aerosol delivery' has been described in many inventions and is fraught with numerous problems that are outlined below:

(1) First of all, the catheter device obstructs the airway lumen i.e. endotracheal tube or tracheobronchial tree. This results in an increase in the airway resistance. If significant changes are not made in several ventilatory parameters like adjustment of inspiratory flow rate and tidal volume, patients will be at a tremendous risk of sustaining barotrauma with associated

morbidity and mortality. Note that the airway resistance is inversely proportional to the fourth power of radius ($R=1/r^4$; R=resistance, r=radius).

(2) Presence of a catheter in the airway lumen is no different from having a foreign body in the airway. The airway that is already narrow on account of bronchospasm, inflammation and edema (e.g asthma) can develop asphyxia or cessation of airflow on introduction of any catheter device in the airway.

(3) Most catheter devices are introduced in the airway blindly. Using ultrasound of fluoroscopy to see catheter position in the airway as has been suggested in some inventions can be extremely time consuming, labor intensive, expensive and require special training. This would restrict the use to only a handful of providers who would have had specialized training to use the device. Over and above, the greater the time spent by a catheter delivery system in the airways, the greater the problems. Patients with airway obstruction need the delivery of medication instantly for relief of bronchospasm. Failure to do so may result in deleterious effects and even patient death.

(4) Blind introduction of a catheter device into the tracheobronchial tree can lead to injury to airway mucosa. This will result in edema (fluid in airways) hemorrhage (blood) and inflammation (swelling) of the airways. Such damage to the airways can be fatal.

(5) Patients with asthma or chronic obstructive airways disease have hypersensitive airways. Exposure of the airway to any irritant can cause severe bronchospasm. Introduction of a catheter into the airways can first of all cause violent coughing resulting in further damage to the airway mucosa

(edema, hemorrhage and inflammation). Secondly, the catheter can cause severe and intractable bronchaspasm resulting in a significant morbidity and mortality.

(6) All catheter devices when subject to pressure either via a syringe or a pressurized MDI canister develop a phenomenon called 'WHIPPING EFFECT' or 'FLING', where the distal tip of the catheter moves violently squirting the medication non-uniformly in the endotracheal tube or in the proximal airways. Also the 'WHIPPING EFFECT' can cause airways injury. Some inventions have used centering devices to avert this effect. However, the technique of centering the catheter device in such inventions is extremely time consuming and labor intensive. Moreover, problems 1, 2, 3, 4, and 5 as outlined above become even more intensified with the use of centering devices. Use of centering device would also require special training for the health care providers (nurses, respiratory therapists, house-staff physicians, physician assistants, attending physicians). Hence, use of such devices would be limited and not practical.

(7) The catheter size, as determined by the size of the lumen, the thickness of the catheter, and the size of the centering device, may altogether preclude its' use in several patient populations-pediatrics, neonates and adults intubated with smaller size ET tubes.

(8) Also some catheter devices have designed mechanisms to overcome impingement of aerosol particles on the carina of the airway. The use of 'horn' in one invention and 'multiple conduits with plurality of holes' in

others would result in a significant loss of medication by impingement on the horn and multiple conduits itself.

(9) One time use of a catheter device for each treatment would be extremely expensive and impractical. Recurrent use of the same device can lead to introduction of infection into the airways and cause nosocomial pneumonia. Some inventions have used sterile sheaths to protect the catheters when not in use. However, these sheaths do not have any locking mechanism to prevent the secretions from entering the sterile sheaths. Hence, repeated introduction of the catheter device even with use of a sterile sheath can be extremely deleterious and result in an increased incidence of lung infection.

(10) Intubated patients generally require suctioning of airway secretions prior to delivery of medication. This would enable the aerosol particles to reach the distal airways. Presence of a catheter in the airway to deliver medication will interfere with suctioning the airway and hence delivery of medication.

In summary, all catheter delivery devices have numerous problems and chest physicians do not recommend their use in patients at this time. Our invention is a major improvement over all catheter devices as it overcomes all the problems outlined above that are associated with the catheter delivery system.

2. NEBULIZER SYSTEM VERSUS METERED DOSE INHALER (MDI) FOR AEROSOL DELIVERY

There are multiple ways of delivering aerosolized medication to the lungs in intubated and non-intubated patients:

(A) NEBULIZER SYSTEM

(B) MDI

a) SUSPENSIONS

b) SOLUTIONS

c) DRY POWDERS

(C) MDI with a SPACER DEVICE

Each system of aerosol delivery has special characteristics and they all differ significantly from each other in 'dose output' and 'particle size distribution'. Variables that differentiate various aerosol delivery systems are:

(1) Total dose output of the medication

(2) Particle size distribution

(3) Total dose administered

(4) Amount of medication wasted in the delivery system

(5) Distribution to the oropharynx

(6) Distribution to the gastrointestinal tract

(7) Distribution to the proximal airways

(8) Distribution to the distal airways

(9) Cost of the medication

(10)Cost of the delivery system-equipment and labor.

In addition, within each individual delivery system there are numerous variables that make them different from each other.

(A) Nebulizer System: The medication can be nebulized with the help of an electrical compressor, pressurized air source which may be a wall source or an air tank, a regular syringe or a special syringe designed to generate high pressure, or other mechanical devices. Also different types of gases (air, oxygen, helium, nitrogen, etc.) may be used to nebulize the medication. There are currently over one hundred types of nebulizer systems that are available for aerosol delivery. All the variables outlined will change the characteristics of the aerosol delivery and result in a different 'dose output' and 'particle size distribution'.

In the prior art inventions, some systems use mechanical nebulizers, some use a regular syringe and others use a gas source. The medication delivery in each case would be different. Some systems have shown fluid being propelled with a pump and gas being delivered simultaneously from a pressurized source in proximity to the liquid in order to nebulize it. Some systems have achieved this through catheter systems while others have used conduits in the ET tube. Majority have nebulized medication in the lumen of ET tube resulting in loss of a significant proportion of the medication. Others have done it via catheter system in the tracheobronchial tree, a system which

has innumerable problems mentioned in our discussion on 'Catheter System for Aerosol Delivery-Pitfalls and Problems'.

(B) **Metered Dose Inhalers (MDIs) with or without Spacers**

MDI canisters contain medication in the form of a suspension, a solution or dry powder. Each commercially available MDI has a specific valve, a specific stem of that valve, a specific size nozzle at the tip of that stem, and a specific actuator. Actuation of MDI canister results in a precise depression of the stem of the valve resulting in a specific particle size distribution and dose output from the nozzle of the valve stem. Each of the variables mentioned above affect dose output, particle size and it's distribution. Of the various MDI valves (25 µl, 50 µl, 63 µl, and 100 µl) that are currently available, the majority of commercially available MDI canisters use either 50 µl or 63µl valves.

None of the prior art inventions have described a delivery system with an actuator/adapter that not only perfectly fits the stems of all commercially available valves but also depresses the stems with a high degree of precision. Our invention describes an innovative delivery system that meets all the above specifications that are critical for a specific dose output and particle size distribution.

In summary, nebulizers and MDIs are two aerosol delivery systems that are a world apart and it would be inappropriate to consider the two distinct systems interchangeable or classify them under the same category. Hence, all inventions that have used a nebulizer system to deliver medication are totally

different from our invention which uses only MDI for aerosol delivery. The dose output, particle size and particle distribution of our invention is not only significantly different from all the nebulizer systems but also markedly different from other invention that have used MDIs as a delivery system. The total medication used with our system is significantly lower without any waste and the dose delivered is significantly higher compared to the nebulizers and other MDI delivery systems. Our system results in a nearly 100% delivery of medication directly to the tracheobronchial tree which makes us distinct from other inventions. The time required to administer the medication is just a few seconds, the system is user friendly (easy to administer medication with no specialized training required for the provider) quite unlike other delivery systems (nebulizers and MDIs alike). Over and above the cost of our delivery system (medication cost, the cost of the equipment and labor costs) is substantially lower compared to all the pre-existing nebulizer delivery systems as well as MDI delivery systems.

3. Endotracheal Tubes with Conduits or Secondary Canalizations

Endotracheal tubes with 'conduits' or 'secondary canalizations', as we have described in our invention, overcomes the problems associated with the catheter delivery system. However, if the 'secondary canalizations' are designed inappropriately, as described in some of the inventions, the device will fail to deliver the aerosol particles adequately and not do the job it is designed to do.

Problems that maybe associated with conduits or secondary canalization:

(1) The lumen of the secondary canalization is critical for aerosol particle dose output, adequate particle size and distribution. If the lumen is too small, a high resistance offered will result in a poor dose output. If the lumen is too big, the majority of aerosol particles will adhere to the lumen of secondary canalization and fail to reach the terminal end. A few actuations from the MDI canister would be required before the aerosol particles begin to appear at the distal tip of the canalization, a process which we have called 'Priming of canalization'. The number of actuations required to prime a canalization will depend on the size of the lumen. In our experience, a lumen size between 0.1 mm and 1.0 mm requires no priming and the first actuation of MDI canister results in delivery of medication at the distal tip of the secondary canalization. Any size greater than that may result in poor dose output. Such has been the case with the invention of Matson et al who have worked with secondary canalization with the size of the lumen in the range of 1.14mm to 2.92mm. It is not surprising to see such poor dose output with most of the valves they used with their invention (See Table on page 4 of Matson's invention).

(2) The lumen diameter does not have to be uniform in size throughout the entire length of the secondary canalization. In other words the inner

diameter (ID) can be variable along the length of the secondary canalizations as long as it stays within the defined limits. The rational for changing the diameter is to alter the velocity of aerosol particles, which can further influence their distribution. However, the critical aspect is that in the process of altering the lumen diameter, the inner annular surface or contour of the canalization should remain perfectly smooth. Anything in the design or structure of a device that will result in a change in the smooth contour of the inner annular surface of the secondary canalization will affect the dose output and particle size distribution as the particles will impinge on the protrusions or uneven surface. Our invention meets this pre-requisite with 100% precision as the entire secondary canalization is made of the same material as the ET tube and has a smooth contour. However, in Matson et al's invention, secondary canalization is made of two different materials-plastic and metal. The plastic secondary canalization fuses with a metal tube either midway or near the distal end of the ET tube. As the fusion between the two occurs by insertion of the metal tube in the plastic canalization, there is a loss of the smooth contour of secondary canalization. This would result in a loss of tremendous amount of aerosol particles at the point of protrusion of the metal tube along the entire circumference of secondary canalization. Hence, the result would be poor dose output and altered particle distribution and it is again not surprising why the dose output in their invention was poor with most of the valves.

(3) The secondary canalization can be made by co-extrusion of a plastic material different from that of ET tube. The material chosen should have a co-efficient of friction such that the particles do not stick to the inner annular surface allowing maximum dose output. However, such co-extrusion should not alter the smooth contour of the secondary canalization or alter the size of the ET tube.

(4) One of the most important characteristics of secondary canalization is that it should permit the flow of aerosol particles preferably in one direction. A change in the angle along the length of secondary canalization would result in aerosol particle impingement/trapping on the inner annular surface of the secondary canalization especially along the sharp angles. Also a change in the angle will alter the velocity and flow characteristics of aerosol particles. Our invention takes into account this critical feature and ensures that the flow of aerosol particles is in one direction throughout the course. Problems with some inventions, especially Matson et al's is that the aerosol particles have to change the direction twice at two 90° angles. The first 90° change in the angle is from the vertical part of the metal tube to the horizontal part of the tube. This second 90° change in the angle is from the horizontal part of the metal tube to the exit nozzle. In other words the particles will flow initially in a direction parallel to the longitudinal axis of the ET tube; they will then change their direction to an axis perpendicular to the longitudinal axis of the ET tube; there is then another change in the direction for the particles to now flow in a direction

parallel to the longitudinal axis of the ET tube. Hence, the poor dose output with their invention can be accounted for by loss of a significant proportion of the aerosol particles that get deposited along the first 90° angle and also along the distal end of the horizontal limb of the metal tube past the nozzle.

(5) If the secondary canalization terminates short of the distal tip of the ET tube, a significant proportion of the particles will be deposited in the lumen of the ET tube. In all the inventions till date including Matson et al's, either the secondary canalization terminates in the mid portion or short of the distal tip of the ET tube. In our invention, the secondary canalization terminates at the distal tip of the ET tube with 100% precision. In other words the distal tips of the ET tube and the secondary canalization are identical resulting in no loss of particles in the ET tube lumen.

(6) Secondary canalizations that have a track on the outer annular surface or the inner annular surface of the ET tube will result in an increase in the outer diameter (if lumen diameter of ET tube is constant) or decrease the lumen diameter (if the outer diameter of the ET tube is constant). Also protrusion of any part of the secondary canalization into the main lumen of the ET tube is the biggest drawback as it interferes with numerous functions of the ET tube. Many inventions, especially Matson et al's, suffer tremendously from this pitfall. Outlined are the problems associated with this feature:

(i) Decrease in the ET tube's lumen diameter and lumen area. This would mean a significant increase in the airway resistance for a given constant flow and volume ($R=1/r^4$, R=resistance, r=radius) This could result in an increase in airway pressure and barotrauma if the ventilator flow and volume are not adjusted.

(ii) Suctioning of airway secretions in intubated patients is critical for survival. Protrusion of secondary canalization into the lumen of ET tube will tremendously interfere with suctioning and hence lead to all sorts of problems like airways obstruction and lung collapse.

(iii) Presence of secondary canalization in the lumen of ET tube is a nidus for deposition of secretions and bacterial growth. This would again result in airway obstruction, lung collapse, increased airway pressure, barotrauma, and nosocomial pneumonia.

(iv) A guidewire is generally introduced into the lumen of the ET tube to facilitate intubation. Protrusion of secondary canalization in the lumen of ET tube will interfere with this important function.

(7) Presence of any metal tube or rod anywhere in the ET tube, especially the mid portion or near the distal end would result in loss of pliability of ET tube, which is critical for a smooth intubation. Very often to facilitate intubation the ET tube is bent in the mid portion or terminal portion to match the curvature of patient's airway. Presence of a metal in the ET tube and resultant loss of pliability will greatly interfere with intubation. Over and above the presence of a metal in the mid or distal portion can

cause injury to the airway mucosa, oral cavity and patient's teeth resulting in possible dislodgement. This feature of Matson et al's invention is not only a tremendous drawback but can be extremely hazardous to the patient.

In summary, all the prior art inventions differ from our invention in multiple ways with respect to the features described above under the 3 sections:

1. Catheter System for Aerosol Delivery-Pitfalls and Problems
2. Nebulizer vs. Metered Dose Inhaler (MDI) for Aerosol Delivery
3. Endotracheal Tubes with Conduits or Secondary Canalizations

Our invention overcomes all the pitfalls of the previous inventions and is a significant improvement over all the pre-existing devices. Keeping the key features mentioned above, we will now discuss each reference cited in Question 12 of your correspondence.

A US 6,079,413 6/2000 Baran, George 128/207.14

This is a catheter delivery system utilizing MDI canister to deliver aerosol medication to the respiratory system. Please refer to our discussion on the 'Catheter System for Aerosol Delivery-Pitfalls and Problems' which will highlight the differences between this invention and our invention and also elucidates how our invention is a major

improvement over all the pre-existing devices and overcomes the pitfalls and problems associated with this device.

B US 6,062,223 5/2000 Palazzo et al 128/207.15

This device is not related to our field of invention i.e. delivery of aerosol medication to the lungs. This device is an ET tube designed to facilitate suctioning of the secretions between the inner surface of trachea and outer surface of ET tube especially the secretions above the distal inflatable bulb of ET tube. These secretions generally enter the tracheobronchial tree with a potential risk of causing nosocomial pneumonia. This device is not designed to deliver medications to the lungs and, therefore, should not be included in the reference list of our invention which is primarily designed to deliver aerosol medication to the lungs via ET tube.

C US-6,014,972 1/2000 Sladek, David T. 128/203.12

This device is related to delivery of aerosol medication to airways via MDI but totally different from our invention. It is neither a catheter device nor an endotracheal tube. The device is basically a valved T-connector with an actuator that is inserted into the inspiratory part of the respiratory circuit. This is an old fashioned conventional way of delivering medication to the lungs. The dose output with this delivery system, as demonstrated in many studies is only 10-15%. The majority of aerosol particles get trapped in the inspiratory tubing and the ET tube and very minimal actually reaches the patient's airways. Our invention is first of all an ET tube with aerosol delivery system incorporated in the tube itself. The ET tube in our device comprises of one and/or two

secondary canalizations disposed in the wall of the ET tube to deliver aerosol medication at the tip of the ET tube directly into the tracheobronchial tree without any particles getting trapped in the lumen of ET tube. We have demonstrated a nearly 100% dose output with our device.

D 5,964,223 10/99 Brown, George 128/207.14

This is a catheter delivery system that conveys medication to the distal end of the catheter in liquid form at which location the medicine is nebulized by a pressurized gas or other nebulizing agent. Please refer to our discussions on the 'Catheter System for Aerosol Delivery-Pitfalls and Problems' and 'Nebulizer System vs. Metered Dose Inhaler (MDI) for Aerosol Delivery'. These two sections will highlight the differences between this invention and our invention and demonstrate how the two devices are totally different in structure and principle of operation.

E US-5,499,625 3/96 Frass et al. 128/207.15

This device is not related to our field of invention at all and should not be included in the reference list. This is not an aerosol delivery device. In fact it is not even designed to deliver medication to the lungs. This is an esophageal-tracheal double lumen airway to facilitate mechanical ventilation in patients with 'difficult airway' such that flow from either lumen can be monitored. It is a tool used by anesthesiologists, critical care physicians, and emergency department physicians when faced with a patient who needs intubation and has a 'difficult airway'. Also secondary object of this device is to provide

a combination of ET tube and esophageal obturator ventilation, another modality used in cases of difficult airway. There is no mechanism built into this device to deliver aerosol medication to the lungs.

F US-5,438,982 8/95 Macintyre, Neil R. 128/207.14

This invention relates to endotracheal tube for delivery of liquid solution to the lungs in the form of jet aerosol. The ET tube has two conduits, one for passage of liquid solution and the second for the passage of gas. The two conduits terminate 1-2 cms short of the distal end of ET TUBE. The high velocity of the gas flow from one conduit across the pathway of liquid solution exiting from the distal end of the other conduit creates a jet aerosol. The aerosol medication is mixed and placed in a bag and solution is pumped through one conduit. The second conduit is attached to a gas source to provide a suitably high velocity. The jet aerosol is generated in the lumen of the ET tube. This device is significantly different from our invention as there is no passage of liquid or high velocity gas in our invention. Secondly there is no bag for medication, pump for pumping liquid or gas source for high velocity gas. On the contrary the aerosol particles in our invention are generated by pressurized MDI canister with a metering valve. The secondary canalization in our invention terminates at the tip of the tubular body as a pinhole opening as opposed to this device where two conduits in proximity terminate 1-2 cm before the tip of the ET tube resulting in loss of aerosol particles in the ET tube. Last of all the aerosol in this invention is delivered into the lumen of the ET tube as opposed to

our invention where the aerosol particles are delivered directly in the tracheobronchial tree without any loss in the lumen of the ET tube.

Please refer to our discussions on 'Nebulizer System vs. Metered Dose Inhaler (MDI) for Aerosol Delivery' and 'Endotracheal Tubes with Conduits or Secondary Canalizations' that will highlight the differences between this invention and our invention. In summary, the two devices are totally different in structure and principle of operation.

G US-5,313,939 Gonzales, Rene M. 128/207.14

This invention has been specially designed to deliver medication to the upper airways after the patient has been intubated. This device does not deliver medication to the lower airways which is the focus of our invention. This entire publication focus on the plurality of holes along the annular outer surfaces of ET tube which are in alignment with the plurality of holes in a conduit that extends between the outer annular surface and inner annular surface. These holes provide topical delivery of a substance to patient's upper airway. (Page 2, lines 50-68; Page 3, Lines 1-20). The medication is delivered to the upper airway in liquid or gaseous form (Page 4, line 63) with the help of a syringe, a pump or mechanical means (Page 6, line 5-6). This medication is delivered solely to the upper airway and there is no mechanism of delivery to the distal tracheobronchial tree as described in our invention and as such this device is not relevant to our field of invention.

H US-5,231,983 8/93 Matson et al. 128/207.14

Please refer to our discussion on 'Endotracheal Tubes with Conduits or Secondary Canalizations' where we have discussed the pitfalls of the system. All the problems outlined in this section (7 features and 4 sub-features) are applicable to Matson et al's invention. None of those features apply to our invention. Hence, there are at least 11 reasons how our invention is different from Matson et al's invention. Our invention is a significant improvement over Matson et al's invention as it overcomes all the problems associated with their invention.

Please also refer to our discussion on 'Metered Dose Inhalers with or without Spacers' as a mode of aerosol delivery. We have described a medicament dispenser and a universal adapter in our invention which perfectly fits all a commercially available valve stems resulting in dose output and particle size distribution with a high degree of precision. Such a system has not been described by Matson et al and poor dose outputs with majority of the valves in their publication (see Table on page 4 of their publication) is an evidence for flaw with either secondary canalization and/or actuator/adapter for MDI canister.

I US 5,078,131 Foley, Martin P. 128/207.14 1/92

This device is a catheter system for aerosol delivery. Please refer to our discussion on 'Catheter System for Aerosol Delivery-Pitfalls and Problems' to highlight the differences between this invention and our invention.

J US-5,031.613 Smith et al. 128.207.14

This is a catheter delivery device that is used to aerosolize liquid medication using a syringe at the proximal end. The system is fraught with problems. It is well known to those skilled in the art, that these catheters usually cause the aerosol particles introduced at the proximal end to coalesce during the passage to the distal end and the aerosolized solution thus tends to drip from the distal end. Consequently, delivery of the solution to lung tissue beyond the airways is subsequently defeated by this phenomenon. The internal diameter of the catheter in this invention is too large (3-4 mm) and wall thickness of 1 mm which would occlude all ET tubes up to 6mm in diameter and cause patient death due to airway obstruction. Secondly, liquid instilled into the airways would cause airway irritation, cough, bronchospasm, asphyxia, and airway obstruction and further compromise the respiratory status of the patient.

Please refer to our discussions on 'Catheter System for Aerosol Delivery-Pitfalls and Problems' and 'Nebulizer System vs. MDI for Aerosol Delivery' that will highlight the differences between this invention and our invention.

To overcome some of those problems a drug delivery catheter has been designed by 'Century' (US Patent 5513630, 5542412, 5570686, 579758, 5594987, 5606789). I have given these references in my original patent application. Note this device is only for research purpose and not suitable for everyday use in patients on account of the cost (a few thousand dollars) and need for sterilization after every patient use. Of course, this device is of no practical utility. Over and above even this device is very different from our invention.

K	US	4,976,261	Gluck et al.	128/207.15	12/90

This invention is not related to our field of invention. This invention is related to a novel endotracheal tube to allow prolonged intubation and decrease injury to the tracheobronchial tree due to contact and pressure between the tube and the surrounding mucosa. The multiple lumens in the wall of the tube allow for temperature sensing, gas sampling, pressure sensing and introduction of medication. Of note is that the delivery of medication in this invention is in the form of liquid droplets which is no different from delivery of medication via a syringe into the main lumen of the ET tube. This invention is not designed to deliver aerosolized medication with pressurized MDI canister. Other features of this invention are related to positioning the lumen of the distal portion of ET tube such that the longitudinal axis of the ET tube and trachea are in parallel. There is no proximal port for medication delivery with MDI canister. The opening of the distal tip is located in the primary lumen of ET tube which means that a large portion of the medication would be wasted into the ET tube and not tracheobronchial tree. The distal tip is also described to be protruding into the lumen of the ET tube which would be highly dangerous for several reasons outlined before.

Please refer to our discussions on 'Endotracheal Tubes with Conduits or Secondary Canalizations' and 'Nebulizer System vs. MDI for Aerosol Delivery' that will highlight the differences between this invention and our invention.

I sincerely hope that you will find our response and the necessary amendments in the revised application satisfactory and approve our patent application. I would once

again like to thank you for your invaluable comments and especially the tremendous patience that you demonstrated during our discussion on 2/13/03. If there is anything in this response that needs further clarification, please do not hesitate to contact me any time at 718-519-3968.

Sincerely,

Sunil Dhuper, MD

Fax

To: MITAL B. PATEL From: SUNIL DHUPER MD

Fax: 703 306 4520 Pages: 73 (including cover sheet)

Phone: 703 306 5444 Date: 5/20/03

R : Application # 10/072,282 CC:

☐ Urgent ☑ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

• Comments: Dear Examiner Patel,

As per our conversation, I am faxing 73 pages (including the cover sheet) regarding application 10/072,282. The inclusions are as follows:

1 Page - Express Mail Receipt

1 Page - US Postal Office Transaction Receipt ($17.85 charged)

1 Page - Confirmation from US Postal Service regarding delivery

7 Pages - Response from USPTO (2/4/03)

6 Pages - Response from USPTO (3/6/03)

24 Pages - My response to the two letters from USPTO

17 Pages - Revised Application

15 Pages - Marked up old Application.

If there are any questions, please do not hesitate to call me. Thanks.

2761

EXPRESS MAIL
UNITED STATES POSTAL SERVICE®

POST OFFICE TO ADDRESSEE

ET073990941US

Customer Copy
Label 11-B August 2000

SEE REVERSE SIDE FOR SERVICE GUARANTEE AND INSURANCE COVERAGE LIMITS

MAR 1 2003

ORIGIN (POSTAL USE ONLY)

PO ZIP Code: 11568	Day of Delivery: ☐ Next ☐ Second	Flat Rate Envelope: ☐	
Date In: Mo 3 Day 1 Year 03	☐ 12 Noon ☐ 3 PM	Postage: $ 17.15	
Time In: ☐ AM 4:29 ☐ PM	Military: ☐ 2nd Day ☐ 3rd Day	Return Receipt Fee	
Weight: lbs. 5 ozs. 13	Int'l Alpha Country Code	COD Fee	Insurance Fee
No Delivery: ☐ Weekend ☐ Holiday	Acceptance Clerk Initials	Total Postage & Fees: $ 17.15	

☐ WAIVER OF SIGNATURE (Domestic Only) Additional merchandise insurance is void if waiver of signature is requested. I wish delivery to be made without obtaining signature of addressee or addressee's agent (if delivery employee judges that article can be left in secure location) and I authorize that delivery employee's signature constitutes valid proof of delivery.

NO DELIVERY: ☐ Weekend ☐ Holiday — Customer Signature

CUSTOMER USE ONLY

METHOD OF PAYMENT
Express Mail Corporate Acct. No.

Federal Agency Acct. No. or Postal Service Acct. No.

FROM: (PLEASE PRINT) PHONE (516) 626-3429

SUNIL DHUPER, MD
47 RED GROUND ROAD
OLD WESTBURY, NY 11568

TO: (PLEASE PRINT) PHONE ( )

PATEL, MITAL B.
EXAMINER
UNITED STATES PATENT & TRADEMARK OFFICE
WASHINGTON D.C. 20231

ZIP + 4: 2 0 2 3 1 + [ ] [ ] [ ] [ ]

FOR PICKUP OR TRACKING CALL 1-800-222-1811 www.usps.com USPS

UNITED STATES POSTAL SERVICE

***** WELCOME TO *****
JEROME AVE. STA.
BRONX, NY 10468-9998
03/11/03 04:29PM

Store	USPS	Trans	139
Wkstn	sys5002	Cashier	KN4QSQ
Cashier's Name		E.	
Stock Unit Id		SIAMCDUFFIE	
PO Phone Number		18002758777	
USPS #		3558250123	

1. Exp. Mail PO-ADD 17.85
Destination: 20231
Weight: 12.70oz
Postage Type: PVi
Total Cost: 17.85
Base Rate: 17.85
Label#:
ET073990941US

Subtotal 17.85
Total 17.85

CreditCard 17.85

Number of Items Sold: 1

Confirm Your deliver
Deliver Confirmation
Starting as low as .35 Cents

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,282	02/11/2002	Sunil Kumar Dhuper		1776

7590 02/04/2003

SUNIL DHUPER
47, RED GROUND ROAD
OLD WESTBURY, NY 11568

EXAMINER	
PATEL, MITAL B	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 02/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	DHUPER ET AL.
	10/072,282	
	Examiner	Art Unit
	Mital B. Patel	3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 February 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Application/Control Number: 10/072,282
Art Unit: 3761

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "6" has been used to designate both endotracheal tube and balloon. See page 11 of the specification. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "8" has been used to designate both proximal flexible part and primary cannula. See page 11 of the specification. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "13" has been used to designate both higher level and opening. See page 11 of the specification. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. As set forth by claims 1 and 2, it is unclear as to what exactly is meant by provision, specifically with respect to structure.

7. There is a lack of antecedent basis for the following limitations:

- Claim 2, line 5, "the nozzle"
- Claim 2, line 6, "the origin"
- Claim 2, line 8, "the distal tip"
- Claim 2, line 9 , "the secondary **cannulation**"
- Claim 2, line 9, "the main tubular structure"
- Claim 2, line 10, "the wall"
- Claim 2, line 11, "the distal tip"
- Claim 2, lines 11-12, "the cannulation"
- Claim 2, line 12, "the body"
- Claim 2, line 13, "the outer surface"
- Claim 2, line 13, "the inner surface"
- Claim 2, line 13, "the wall"

Claim Rej ctions - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Matson et al (US 5231983).

10. **As to claim 1**, Matson teaches an endotracheal tube **20** with an expandable balloon cuff **28** at its distal end with a primary cannula **30** for inflation and deflation of the balloon cuff, with a coupling **36** adapted to connect to a syringe; with a provision **24** for a connector at its proximal end to be connected to a ventilator.

11. **As to claim 2**, Matson teaches an endotracheal tube **20** with aerosol delivery apparatus **58** with provision **40** for aerosol delivery of medication to the lungs via a metered dose inhaler (MDI) with at least one secondary canalization **38**; with provision **24** for an adapter at its proximal end; with an adapter **54** designed to fit a nozzle of MDI canister at its proximal end; an adapter with a pinhole (**See Fig. 3**) opening at its distal end that marks an origin of a secondary cannula; the secondary canalization with an ID small enough for the aerosol particles generated by a MDI at the proximal end to be delivered at a distal tip of the ET tube in aerosol form; the secondary cannulation with two parts- a semi-flexible or semi-rigid structure outside a main tubular structure and a rigid track within a wall of the ET tube; the secondary canalization with only one opening at the distal tip of the ET tube without protrusion of the cannulation beyond the body of

the ET tube; the secondary canalization with a track from the outer surface to the inner surface within the wall of the ET tube (**See Figs. 1 and 3**).

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6079413, US 6062223, US 6014972, US 5964223, US 5499625, US 5438982, US 5313939, US 5078131, US 5031613, and US 4976261.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703-306-4520 for regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

WEILUN LO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

mbp
January 25, 2003

Notice of References Cited	Application/Control No. 10/072,282	Applicant(s)/Patent Under Reexaminati n DHUPER ET AL.	
	Examiner Mital B. Pat l	Art Unit 3761	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-6,079,413	06-2000	Baran, George	128/207.14
	B	US-6,062,223	05-2000	Palazzo et al.	128/207.15
	C	US-6,014,972	01-2000	Sladek, David T.	128/203.12
	D	US-5,964,223	10-1999	Baran, George	128/207.14
	E	US-5,499,625	03-1996	Frass et al.	128/207.15
	F	US-5,438,982	08-1995	MacIntyre, Neil R.	128/207.14
	G	US-5,313,939	05-1994	Gonzalez, Rene M.	128/207.14
	H	US-5,231,983	08-1993	Matson et al.	128/207.14
	I	US-5,078,131	01-1992	Foley, Martin P.	128/203.15
	J	US-5,031,613	07-1991	Smith et al.	128/207.14
	K	US-4,976,261	12-1990	Gluck et al.	128/207.15
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,282	02/11/2002	Sunil Kumar Dhuper		1776

7590 03/06/2003

SUNIL DHUPER
47, RED GROUND ROAD
OLD WESTBURY, NY 11568

EXAMINER	
PATEL, MITAL B	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 03/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

MT

Interview Summary	Application No.	Applicant(s)	
	10/072,282	DHUPER ET AL.	
	Examiner	Art Unit	
	Mital B. Pat l	3761	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Mital B. Patel*. (3)_____.

(2) *Mr. Sunil Dhuper (Pro Se)*. (4)_____.

Date of Interview: *13 February 2003* .

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☐ No.
If Yes, brief description: _____ .

Claim(s) discussed: *1 and 2* .

Identification of prior art discussed: *Matson et al (US 5231983)* .

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *The Applicant contacted the Examiner to get clarification on the Office Action. The Applicant also discussed the prior art rejection and explained to the Examiner how the prior art differed from the Applicant's invention. The Examiner explained to the Applicant that the differences need to be set forth in the claims and claim language and that the intended use of the device needs to result in structural differences between the prior art and the Applicant's invention.* .

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i)☐ It is not necessary for applicant to provide a separate record of the substance of the interview(if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

WEILUN LO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

Examiner Note: Y u must sign this form unless it is an Attachment to a signed Offic action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)
In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Revised Notice*
AMENDMENTS MAY NOW BE SUBMITTED IN REVISED FORMAT

The United States Patent and Trademark Office (USPTO) is permitting applicants to submit amendments in a revised format as set forth below. Further details of this practice are described in *AMENDMENTS IN A REVISED FORMAT NOW PERMITTED*, signed January 31, 2003, expected to be published in *Official Gazette* on February 25, 2003 (Notice posted on the Office's web site at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm). The revised amendment format is essentially the same as the amendment format that the Office is considering adopting via a revision to 37 CFR 1.121 (Manner of Making Amendments). The revision to 37 CFR 1.121 (if adopted) will simplify amendment submission and improve file management. The Office plans to adopt such a revision to 37 CFR 1.121 by July of 2003, at which point compliance with revised 37 CFR 1.121 will be mandatory.

Effective immediately, all applicants may submit amendments in reply to Office actions using the following format. Participants in the Office's electronic file wrapper prototype[1] receiving earlier notices of the revised practice may also employ the procedures set out below.

REVISED FORMAT OF AMENDMENTS

Begin on separate sheets:
Each section of an Amendment (e.g., Claim Amendments, Specification Amendments, Drawing Amendments, and Remarks) should begin on a separate sheet. *For example*, in an amendment containing a.) introductory comments, b.) amendments to the claims, c.) amendments to the specification, and d.) remarks, each of these sections must begin on a separate sheet. This will facilitate the process of separately indexing and scanning of each part of an amendment document for placement in an electronic file wrapper.

Two versions of amended part(s) no longer required:
The current requirement in 37 CFR 1.121(b) and (c) to provide two versions (a clean version and a marked up version) of each replacement paragraph, section or claim will be waived where an amendment is submitted in revised format below. The requirements for substitute specifications under 37 CFR 1.125 will be retained.

A) **Amendments to the claims:**
Each amendment document that includes a change to an existing claim, or submission of a new claim, **must include a complete listing** of all claims in the application. After each claim number, the status must be indicated in a parenthetical expression, and the text of each claim under examination (with markings to show current changes) must be presented. The listing will serve to replace all prior versions of the claims in the application.

(1) The current status of all of the claims in the application, including any previously canceled or withdrawn claims, must be given. Status is indicated in a parenthetical expression following the claim number by one of the following: (original), (currently amended), (previously amended), (canceled), (withdrawn), (new), (previously added), (reinstated – formerly claim #_), (previously reinstated), (re-presented – formerly dependent claim #_), or (previously re-presented). The text of all pending claims under examination must be submitted each time any claim is amended. Canceled and withdrawn claims should be indicated by only the claim number and status.

(2) All claims being currently amended must be presented with markings to indicate the changes that have been made relative to the immediate prior version. The changes in any amended claim should be shown by strikethrough (for deleted matter) or underlining (for added matter). An accompanying clean version is not required and should not be presented. Only claims of the status "currently amended" will include markings.

(3) The text of pending claims not being amended must be presented in clean version, i.e., without any markings. Any claim text presented in clean version will constitute an assertion that it has not been changed relative to the immediate prior version.

---

[1] The Office's Electronic File Wrapper prototype program is described in *USPTO ANNOUNCES PROTOTYPE OF IMAGE PROCESSING*, 1265 *Off. Gaz. Pat. Office* 87 (Dec. 17, 2002) ("Prototype Announcement"), and applies only to Art Units 1634, 2827 and 2834.

UNITED STATES
PATENT AND
TRADEMARK OFFICE

Commissioner for Patents
Washington, DC 20231
www.uspto.gov

FEB 20 2003

Dear Patent Business Customer:

The United States Patent and Trademark Office ("Office") is now permitting and encouraging applicants to voluntarily submit amendments in a revised format as set forth in *AMENDMENTS IN A REVISED FORMAT NOW PERMITTED*, ____ *Off. Gaz. Pat. Office* __ (February 25, 2003), currently available on the USPTO web site at **http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm**. The revised format permits amendments to the specification and claims to be made in a single marked-up version; the requirement for a clean version is eliminated. Attached, you will find a flyer with information and instructions regarding the procedures to be used to comply with the revised format. The flyers are being inserted with out-going Office actions mailed during the period of February 20, 2003 - March 31, 2003.

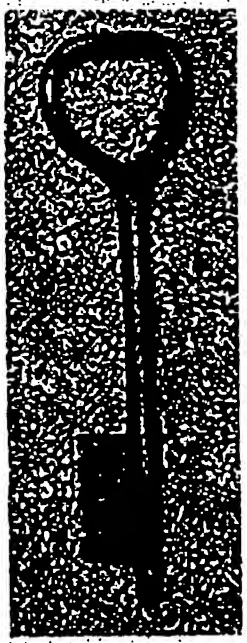
The revised amendment format is essentially the same as the amendment format for the specification, claims, and drawings that the Office is considering adopting via a revision to 37 CFR 1.121 (Manner of Making Amendments). The revision to 37 CFR 1.121 (if adopted) will simplify amendment submission and improve file management. This proposed revision and others necessary to facilitate a gradual transition to the use of an Electronic File Wrapper (EFW) will be set forth in a Notice of Proposed Rule making (NPR), expected to be published by March 2003. After consideration of public comments, the Office anticipates adopting a revision to § 1.121, following publication of a Notice of Final Rule making (NFR), expected by June 2003, at which point compliance with revised § 1.121 will be mandatory.

The Office will continue to accept your amendment submissions in the revised format during the voluntary period, which will extend up to the effective date of final revisions to § 1.121. The Office also encourages your feedback on the proposed revised amendment format and other changes set forth in the NPR, expected to be published by March 2003.

For assistance: Any questions regarding the submission of amendments pursuant to the revised practice should be directed to Office of Patent Legal Administration (OPLA), Legal Advisors Elizabeth Dougherty (**Elizabeth.Dougherty@uspto.gov**), Gena Jones (**Eugenia.Jones@uspto.gov**) or Joe Narcavage (**Joseph.Narcavage@uspto.gov**). Alternately, you may send e-mail to "Patent Practice", the OPLA e-mail address that has been established for receiving queries and questions about patent practice and procedures or telephone OPLA at (703) 305-1616.

Nicholas P. Godici
Commissioner for Patents

Attachment: Flyer entitled: *Revised Notice* AMENDMENTS MAY NOW BE SUBMITTED IN REVISED FORMAT*



TECHNOLOGY CENTER 3700 CUSTOMER ADVISORY

USE OF RIGHTFAX IS THE KEY TO QUICK & EFFICIENT PROCESSING!

OFFICIAL TC 3700 RIGHT FAX NUMBER	(703)872-9302
OFFICIAL TC 3700 AFTER-FINAL FAX NUMBER	(703)872-9303

Next time you get ready to mail us correspondence, consider faxing it to us at the fax numbers above!

Why?

- ✓ **faxes are retrievable if lost**
- ✓ **faxes go directly to the Technology Center for immediate entry as opposed to being handled by several mail distribution areas**
- ✓ **facsimile receipt is automatically sent to user upon receipt of faxed document**

UNITED STATES POSTAL SERVICE

Date: 04/30/2003

Fax Transmission To: Postal Customer
Fax Number: 718-519-3734

Dear Postal Customer:

The following is in response to your 04/30/2003 request for delivery information on your Express Mail item number ET073990941US. The delivery record shows that this item was delivered on 03/12/2003 at 11:07 AM in WASHINGTON, DC 20231 to V REISTER. There is no delivery signature on file for this item.

Thank you for selecting the Postal Service for your mailing needs. If you require additional assistance, please take this receipt to your local Post Office or postal representative.

Sincerely,

United States Postal Service

EXPRESS MAIL
UNITED STATES POSTAL SERVICE®

POST OFFICE TO ADDRESSEE

ET073990941US

Customer Copy
Label 11-B August 2000

SEE REVERSE SIDE FOR SERVICE GUARANTEE AND INSURANCE COVERAGE LIMITS

MAR 1 2003

ORIGIN (POSTAL USE ONLY)

PO ZIP Code: 11568	Day of Delivery: ☐ Next ☐ Second	Flat Rate Envelope: ☐	
Date In: Mo. 3 Day 1 Year 03	☐ 12 Noon ☐ 3 PM	Postage: $ 1.75	
Time In: ☐ AM 4:29 ☐ PM	Military: ☐ 2nd Day ☐ 3rd Day	Return Receipt Fee	
Weight: lbs. 3 ozs.	Int'l Alpha Country Code	COD Fee	Insurance Fee
No Delivery: ☐ Weekend ☐ Holiday	Acceptance Clerk Initials	Total Postage & Fee: $ 17.85	

☐ WAIVER OF SIGNATURE (Domestic Only): Additional merchandise insurance is void if waiver of signature is requested. I wish delivery to be made without obtaining signature of addressee or addressee's agent (if delivery employee judges that article can be left in secure location) and I authorize that delivery employee's signature constitutes valid proof of delivery.

NO DELIVERY: ☐ Weekend ☐ Holiday

Customer Signature

CUSTOMER USE ONLY

METHOD OF PAYMENT
Express Mail Corporate Acct. No.

Federal Agency Acct. No. or Postal Service Acct. No.

FROM: (PLEASE PRINT) PHONE (516) 626-3439

SUNIL DHUPER, MD
47 RED GROUND ROAD
OLD WESTBURY, NY 11568

TO: (PLEASE PRINT) PHONE ( )

PATEL, MITAL B.
EXAMINER
UNITED STATES PATENT & TRADEMARK OFFICE
WASHINGTON D.C. 20231

ZIP + 4: 20231 +

FOR PICKUP OR TRACKING CALL 1-800-222-1811 www.usps.com

EMS